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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

J. Kevin DONAHUE

Serial No. 09/977,865

Filed: October 15, 2001

For: **Methods and Compositions for
Nucleic Acid Delivery**

)
)
) Group Art Unit: 1636
)
) Examiner: K. Katcheves
)
)
)
) Atty. Docket No. 001107.00449

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Post Office Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Submitted herewith are three (3) sheets of Form PTO-1449. A copy of each of the non-patent references listed therein is enclosed. It is respectfully requested that the Examiner make his/her consideration of each of these documents formally of record.

The Commissioner is authorized to charge \$180.00 to effect entry of this Information Disclosure Statement to Deposit Account 19-0733. Further, the Commissioner is authorized to charge any additional fees which may be required or credit any overpayment to our Deposit Account 19-0733.

05/26/2004 YPOLITE1 00000054 190733 09977865
01 FC:1806 180.00 DA

Respectfully submitted,

Dated: May 24, 2004

By: Sarah A. Kagan
Sarah A. Kagan
Registration No. 32,141

Banner & Witcoff, Ltd.
Customer No. 22907



PTO/SB/08a (05-03)

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 1 of 3

Complete if Known

Application Number	09/977,865
Filing Date	October 15, 2001
First Named Inventor	J. Kevin DONAHUE
Art Unit	1636
Examiner Name	K. Katcheves
Attorney Docket Number	001107.00449

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		2002/0094326 A1	07/18/2002	Donahue et al.	
		6,100,270	08/08/2000	Campbell	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		WO 96/16657	06/06/1996	Campbell		
		WO 99/19792	04/22/1999	Lawrence		
		WO 99/31982	07/01/1999	Stedman		

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Lamping, K. et al., "Agonist-specific impairment of coronary vascular function in genetically altered, hyperlipidemic mice," <i>Am. J. of Phys.</i> , (April 1999), pp. R1023-R1029, Vol. 276, no. 4	
		Kuwahara, A. et al., "5-HT activates nitric oxide-generating neurons to stimulate chloride secretion in guinea pig distal colon," <i>Am. J. Phys.</i> , (October 1998), pp. G829-G834, Vol. 275, no. 4	
		Frieden, M. et al., "Effect of 5-hydroxytryptamine on the membrane potential of endothelial and smooth muscle cells in the pig coronary artery," <i>British Journal of Pharmacology</i> , (1995), pp. 95-100, Vol. 115, no. 1	
		Reiser, G., "Nitric oxide formation caused by calcium release from internal stores in neuronal cell line in enhanced by cyclic amp," <i>European Journal of Pharmacology Molecular Pharmacology Section</i> , (1992), pp. 89-93, Vol. 9, no. 1	
		Katz, S. et al., "Acute type 5 phosphodiesterase inhibition with sildenafil enhances flow-mediated vasodilation in patients with chronic heart failure," <i>Journal of the American College of Cardiology</i> , (September 2000), pp. 845-851, Vol. 36, No. 3	

Examiner
SignatureDate
Considered

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**INFORMATION DISCLOSURE
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Sheet 2 of 3

Complete if Known

Application Number	09/977,865
Filing Date	October 15, 2001
First Named Inventor	J. Kevin DONAHUE
Art Unit	1636
Examiner Name	K. Katcheves
Attorney Docket Number	001107.00449

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Lai, N.C. et al., "Sodium nitroprusside facilitates intracoronary gene transfer in pigs," <i>Faseb Journal</i> , (March 2001), p. A100, Vol. 15, No. 4	
		Bilbao, R. et al., "A blood-tumor barrier limits gene transfer to the experimental liver cancer: The effect of vasoactive compounds," <i>Gene Therapy</i> , (November 2000), pp. 1824-1832, Vol. 7, no. 21	
		Corbin, J.D., et al., "Pharmacology of Phosphodiesterase-5 Inhibitors," <i>IJCP</i> , (July/August 2002), pp. 453-459, Vol. 56, No. 6	
		Eardly, I. et al., "Tadalafil (Cialis) for Men with Erectile Dysfunction," <i>IJCP</i> , (May 2002), pp. 300-304, Vol. 56, No. 4	
		Donahue, J.K. et al., "Ultrarapid, highly efficient viral gene transfer to the heart," <i>PNAS</i> , (April 1997), pp. 4664-4668, Vol. 94	

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SignatureDate
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		Donahue, J.K. et al., "Acceleration of widespread adenoviral gene transfer to intact rabbit hearts by coronary perfusion with low calcium and serotonin," <i>Gene Therapy</i> , (1998), pp. 630-634, Vol. 5	
		Hetman, J.M. et al., "Cloning and characterization of PDE7B a cAMP-specific phosphodiesterase," <i>PNAS</i> , (January 2004), pp. 472-476, Vol. 97, No. 1	
		Nagata, K. et al., "Phosphodiesterase Inhibitor-mediated Potentiation of Adenovirus Delivery to Myocardium," <i>J. Mol. Cell Cardiol.</i> , (2001), pp. 575-580, Vol. 33	
		Sung, B. et al., "Structure of the catalytic domain of human phosphodiesterase 5 with bound drug molecules," <i>Nature</i> , (September 2003), pp. 98-102, Vol. 425	
		Lenhart, S.E. et al., "Preservation of myocardial function after adenoviral gene transfer in isolated myocardium," <i>Am. J. Physiol. Heart Circ. Physiol.</i> , (2000), pp. H986-H991, Vol. 279	
		Rotella, D., "Phosphodiesterase 5 Inhibitors: Current Status and Potential Applications," <i>Nature</i> , (September 2002), pp. 674-682, Vol. 1	
		Soderling, S.H. et al., "Cloning and characterization of a cAMP-specific cyclic nucleotide phosphodiesterase," <i>PNAS</i> , (July 1998), pp. 8991-8996, Vol. 95	
		Barr, E. et al., "Efficient catheter-mediated gene transfer into the heart using replication-defective adenovirus," <i>Gene Therapy</i> , (January 1994), pp. 51-8, Vol. 1, No. 1 (Abstract Only)	
		Ding, Z. et al., "A minimally invasive approach for efficient gene delivery to rodent hearts," <i>Gene Therapy</i> , (February 2004), pp. 260-265, Vol. 11, No. 3 (Abstract Only)	
		Inoue H. et al., "T-1032, a novel specific phosphodiesterase type 5 inhibitor, increases venous compliance in anesthetized rats," <i>Eur J. Pharmacol.</i> , (June 2001), pp. 109-114, Vol. 422, No. 1-3 (Abstract Only)	
		Takagi, M. et al., "Pharmacological profile of T-1032, a novel specific phosphodiesterase type 5 inhibitor, in isolated rat aorta and rabbit corpus cavernosum," <i>Eur J. Pharmacol.</i> , (January 2001), pp. 161-168, Vol. 411, No. 1-2 (Abstract Only)	

Examiner
SignatureDate
Considered

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180

Complete if Known

Application Number	09/977,865
Filing Date	October 15, 2001
First Named Inventor	J. Kevin DONAHUE
Examiner Name	K. Katcheves
Art Unit	1636
Attorney Docket No.	001107.00449

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money ☐ Other ☐ None
Order

☒ Deposit Account:

Deposit
Account
Number

19-0733

Deposit
Account
Name

Banner & Witcoff, LTD.

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments
☒ Charge any additional fee(s) during the pendency of this application
☐ Charge fee(s) indicated below, except for the filing fee
to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1)

(\$ 0)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		-	**	=	0	X		=	0
Independent Claims		-	**	=	0	X		=	0
Multiple Dependent						X		=	0

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2)

(\$ 0)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3)

(\$ 180)

SUBMITTED BY

Complete (if applicable)

Name (Print/Type)	Sarah A. Kagan	Registration No. (Attorney/Agent)	32,141	Telephone	202.824.3000
Signature		Date	May 24, 2004		

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